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10/646,903	08/22/2003	Daniel M. Lieberman	3998P2652	1335
23504	7590	11/14/2007		
WEISS & MOY PC 4204 NORTH BROWN AVENUE SCOTTSDALE, AZ 85251			EXAMINER MACNEILL, ELIZABETH	
			ART UNIT 3767	PAPER NUMBER
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

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**BEFORE THE BOARD OF PATENT APPEALS  
AND INTERFERENCES**

Application Number: 10/646,903  
Filing Date: August 22, 2003  
Appellant(s): LIEBERMAN, DANIEL M.

**MAILED**  
**NOV 14 2007**  
**GROUP 3700**

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Jeffrey Weiss  
For Appellant

**EXAMINER'S ANSWER**

This is in response to the appeal brief filed 28 September 2007 appealing from the  
Office action mailed 28 March 2007.

**(1) Real Party in Interest**

A statement identifying by name the real party in interest is contained in the brief.

**(2) Related Appeals and Interferences**

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

**(3) Status of Claims**

The statement of the status of claims contained in the brief is correct.

**(4) Status of Amendments After Final**

No amendment after final has been filed.

**(5) Summary of Claimed Subject Matter**

The summary of claimed subject matter contained in the brief is correct.

**(6) Grounds of Rejection to be Reviewed on Appeal**

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

**(7) Claims Appendix**

The copy of the appealed claims contained in the Appendix to the brief is correct.

**(8) Evidence Relied Upon**

6,605,036

WILD

8-2003

Dardik, A et al. "Subdural hematoma after thoracoabdominal aortic aneurysm repair"

Journal of Vascular Surgery, vol36, no 1 (2002 July), pp. 47-50

Declaration under 37 CFR 1.132 of Dan Lieberman, M.D. filed 20 February 2007

**(9) Grounds of Rejection**

***Claim Rejections - 35 USC § 102***

1. The following is a quotation of the appropriate paragraphs of 35.U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims are rejected under 35 U.S.C. 102(e) as being anticipated by WILD (US 6,605,036).

Regarding claims 11,14-16, Wild teaches a method and apparatus for treating a subdural hematoma (Col 1 line 53) comprising a dual lumen catheter (1) with a passive drainage channel (10) with perforations (at distal end) and multiple irrigation channels (9) with perforations (at distal end).

Regarding claim 17, the drainage perforations have a diameter of less than 2mm (Col 12 line 28)

Regarding claim 18 and 19, a pressure valve is coupled to the irrigation channel ("A pressure and volume monitoring system of conventional construction is preferred for this purpose", Col 7 line 60)

Regarding claims 20 and 21, "The passive fluid escape channel is connected proximally to a drainage tube providing gravity drainage and collection of all fluids."  
(Col 7 line 46)

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Regarding claim 22, a hole is drilled in the skull to access the subdural space (inherent to accessing the subdural space)

Regarding claim 23, a tuohy needle is provided (outer tube 25)

Regarding claim 24, a guidewire is provided (steerable push-pull wires)

Regarding claim 25, a stylette is provided (rigid telescope 2 functions in the same manner as a stylette, to provide temporary rigidity to the catheter)

***Claim Rejections - 35 USC § 103***

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 26 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wild as applied to claim 14 above, and further in view of DARDIK et al (Journal of Vascular Surgery).

Wild teaches the limitations of the dual lumen catheter as above, but is silent on the duration of irrigation and drainage of the subdural hematoma.

Dardik et al teach that drains are removed from patients after three days (Abstract).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the dual lumen catheter for three days, as taught by Dardik et al, as a well known medical procedure.

**(10) Response to Argument**

**Claim 11**

Regarding claim 11, applicant has argued that the configuration of the drainage and irrigation tubes taught in Wild does not meet the claim limitation that “the plurality of tubes supports the irrigation channel inside the drainage channel.” Fig 17a and 17b of Wild shows the arrangement of drainage tube 10 (Col 11 at line 30) and irrigation tubes 9 (Col 11 at line 30) disposed in the bundle 3a (Col 16 line 42). The bundle 3a and the lumen 10 are taken as the “drainage channel” and therefore lumens 9 are within the drainage channel and give “support.” The walls of the bundle do separate the lumens, but they must be separated by some wall otherwise the fluid would mix.

In response to applicant's argument that Wild is not for use to drain a subdural hematoma, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use (as indicated at Col 1 line 53), then it meets the claim.

**Claims 14,15, and 18-22**

Regarding claims 14,15, and 18-22, applicant has argued that Wild does not teach a method of draining and irrigating a subdural hematoma. Wild discloses that his device is “a surgical instrument for use in endoscopic surgery, particularly endoscopic neurosurgery (Col 1 line 10)” and that such devices are used for draining subdural hematomas (Col 1 line 52). The declaration filed 20 February 2007 addressed the

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assertion that Wild's device would not be flexible enough for drainage, but Wild specifically points out that his device may be rigid or flexible (Col 6 line 37). Wild's use of irrigation fluid to clear debris from the lens of the endoscope meets the limitation of "irrigating said subdural space." The drainage channel is passive and uses gravity to drain fluids, and is therefore always open and draining either the irrigate or the subdural fluid (Col 7 line 45-end).

**Claims 16-17**

Regarding claims 16 and 17, it is also noted that the endoscopic camera is readily removable from the device (via channel 7, Col 11 paragraph at line 20).

**Claim 23**

Regarding claim 23, applicant has argued that Wild does not teach a Tuohy needle. A Tuohy needle is a needle which allows a catheter to exit at a 45-degree angle. See Fig 13 of Wild. Additionally, no structural limitations are given to the needle.

**Claim 24**

Regarding claim 24, applicant has argued that Wild does not teach a guide wire. The push-pull wires (Col 6 line 40) are used to direct the catheter into position in the subdural space. This meets the claim limitations of advancing the catheter along the guide wire into the subdural space.

**Claim 25**

Regarding claim 25, applicant has again provided no structural limitations in the claim to define the "stylette." Anything which is removable and gives the catheter rigidity would meet the claim, such as *rigid* telescope 2.

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**Claims 26-27**

Regarding claims 26-27 rejected under 35 U.S.C. 103(a) applicant has argued that Dardik does not teach removing subdural hematoma drains being removed after 3 days. However, the drains were used to treat subdural hematomas and therefore one of ordinary skill in the art would recognize that drainage may take 3 days.

**(11) Related Proceeding(s) Appendix**

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

Elizabeth MacNeill

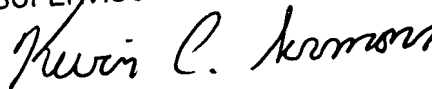


10/30/07

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